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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/559,372

11/28/2006

Robert Price

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POLSINELLI SHUGHART PC

700 W. 47TH STREET

SUITE 1000

KANSAS CITY, MO 64112-1802

EXAMINER

BLIZZARD, CHRISTOPHER JAMES

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



<b>Office Action Summary</b>	<b>Application No.</b> 10/559,372	<b>Applicant(s)</b> PRICE ET AL.	
	<b>Examiner</b> CHRISTOPHER BLIZZARD	<b>Art Unit</b> 3771	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 44-95 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44-95 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/8/07, 6/8/07</u> . | 6) <input type="checkbox"/> Other: _____  |



### **DETAILED ACTION**

1. This office action is in response to preliminary amendment files 12/6/05. As directed claims 1-48 were cancelled and claims 49-95 added. Therefore this application currently has claims 49-95 pending.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 49-59, 61-66, 68-70, 72, 73, 76-82, 84-89, and 91-95 are rejected under 35 U.S.C. 102(b) as being anticipated by Hills (6,482,391).

4. Regarding claim 49, Hills discloses a delivery device for a medicament comprising a housing (fig. 1), a receptacle (5) for holding a medicament in the form of a powder (column 3, lines 46-53), a source of propellant (4) in the form of a canister of gas (fig. 2), wherein the housing has an inlet (11) and an outlet (12) for the receptacle, wherein the inlet is in fluid communication with the source of propellant (fig. 2) and the inlet is directed against the medicament (fig. 2) and the outlet is spaced from the medicament to allow aerosolization of the medicament (fig. 2).

5. Regarding claims 50 and 51, Hills discloses the receptacle and the source of propellant being removable from the housing (column 3 ,lines 58-60).



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6. Regarding claims 52 and 53, Hills discloses a fluid pathway (9) between the inlet and the source or propellant, having a choke (fig. 2, around #7) in the form of a restriction that would decelerate the flow of propellant.

7. Regarding claims 54-57, Hills discloses the inlet being an inlet tube extending into the receptacle having an end directed toward the medicament with a flared opening or perforation (fig. 2).

8. Regarding claims 58 and 59, Hills discloses the receptacle having a bottom containing the medicament and a top which connects to the housing and the outlet is arranged to open into the receptacle at the top of the receptacle and is substantially flush with the top of the receptacle (column 4, lines 7-10).

9. Regarding claim 61, Hills discloses the outlet being formed as a hole in the housing which is in fluid communication with an outlet pathway in the housing which connects to the exterior of the housing (fig. 2, path between 12 and 14).

10. Regarding claim 62, Hills discloses a stable aerosol of medicament being formed upon activation of the device (column 4, lines 11-15).

11. Regarding claim 63, Hills discloses the device wherein the outlet is normally sealed by a valve until a critical pressure is reached (column 4, lines 18-21).

12. Regarding claims 64 and 65, Hills discloses the outlet pathway containing chokes in the form of the diameter of the outlet pathway constricting, which would decelerate the medicament (fig. 2, around #13).

13. Regarding claim 66, Hills discloses the device having a mouthpiece (14).



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14. Regarding claim 68, Hills discloses the device being a handheld device (column 4, lines 19-21).

15. Regarding claims 69 and 70, Hills discloses the canister of gas having a valve (6), and inherently could be arranged above the canister since the device is handheld and its orientation can be easily manipulated.

16. Regarding claims 72 and 73, Hills discloses the claimed housing and receptacle of medicament in the delivery device above.

17. Regarding claims 76-82, 84-89, and 91 Hills discloses the claimed dispensing receptacle; header unit, in the form of the housing; and source of propellant in the above claims.

18. Regarding claim 92-94, Hills discloses the claimed delivery device housing having a first open ended compartment which the source of propellant (4) is received in (fig. 2), and a clip is adapted to receive the dispensing receptacle (column 3, lines 58-60), wherein the clip is associated with a propellant exit connection (7) and the exit connection is arranged to engage with an entry connector (10) for the dispensing receptacle (fig. 2).

19. Regarding claim 95, Hills discloses the method of dispensing medicament as an aerosol to a patient comprising the steps of, providing a receptacle (5) containing powder medicament, discharging pressurized propellant from a canister (4) through a delivery tube (11) extending into the receptacle and directed at the medicament, forming an aerosol by transfer of energy from the propellant to the powder (column 4, lines 14-15), and discharging the aerosol through an outlet passage (12)



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***Claim Rejections - 35 USC § 103***

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claims 60, 75, and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hills (6,482,391).

22. Regarding claims 60 and 83, Hills discloses the claimed device except for the outlet not extending into the receptacle, but does disclose the outlet only extending partway in the receptacle (column 4, lines 7-9). It would have been an obvious matter of design choice to have the out not extend into the receptacle, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

23. Regarding claim 75 Hills discloses the claimed invention except for the receptacle and the propellant canister being linked together. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the receptacle and the propellant canister be linked together, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. Howard v. Detroit Stove Works, 150 U.S. 164 (1893).



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24. Claims 67 and 90 rejected under 35 U.S.C. 103(a) as being unpatentable over Hills (6,482,391) in view of Sladek (6,014,972).

25. Regarding claims 67 and 90, Hills disclose the claimed device but does not disclose the mouthpiece (14) being a tube for engaging with a breathing tube for a patient using a respirator. Sladek teaches a device for adapting an inhaler for engaging with a breathing tube for a patient using a respirator (Abstract, lines 1-3). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the device of Hills with an adapter for engaging an inhaler with a breathing tube of a respirator as taught by Sladek in order to provide the advantage of delivering medication to a patient being mechanically ventilated.

26. Claims 71 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hills (6,482,391) in view of Wetterlin (4,114,615).

27. Regarding claims 71 and 74, Hills discloses the claimed device except for the receptacle being in the form of a plurality of blister packs. Wetterlin teaches a powder medicament device wherein the receptacle is a plurality of blister packs (column 4, lines 59-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide dispenser of Hills with blister packs as taught by Wetterlin in order to provide the advantage of being able to better control the amount of medicament delivered to the user.

### ***Conclusion***

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Samiot (6,125,844) a drug delivery device with a receptacle



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and a propellant source, Braithwaite (7,464,704) a powder medicament dispenser with a blister pack, and Yamashita (7,448,379) a powder inhalation system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday thru Friday, 9:00AM -5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)2724835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BLIZZARD/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771



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